DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Clarence W. Lallier, Owner
Scenic View Farm
9518 Larson Rd.
Cassville, NY 13328

July 15, 2002

File No.: 2002-38

Dear Mr. Lallier:

On June 12, 2002, U.S. Food and Drug Administration investigators conducted an inspection at your cattle dealership located in Cassville, New York. This inspection confirmed that in March 2002 you offered an animal for sale for food that was adulterated within the meaning of Sections 402 (a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed serious deviations from the regulations for Extralabel Drug Use in Animals (Title 21, Code of Federal Regulations, Part 530). These deviations caused an animal drug to become adulterated within the meaning of Section 501(a)(5). You are also in violation of Section 301(h) of the Act in that you provided a false guaranty.

On or about March 4, 2002, you offered for sale a cow identified with ear tag (21)ZEB5281 for slaughter as human food. The cow was sold to and slaughtered at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 2.60 parts per million (ppm) and 0.83 ppm sulfadimethoxine in liver and muscle tissues, respectively.

A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in edible tissues of cattle (Title 21 Code of Federal Regulations 556.640). The presence of this drug in excess of the tolerance in the liver and muscle tissues of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about April 12, 2001 you provided [redacted] a signed Livestock Owner's Certificate. This certificate certified that none of the livestock delivered t[redacted] would be adulterated within the meaning of the Act and that none of the livestock will have an illegal level of drug residues. On or about March 4, 2002, you sold this cow, adulterated with these residues, to [redacted].

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Our investigation also found that you hold animals on your farm under conditions that are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of drugs from edible tissues. Foods from animals held under such conditions are adulterated under Section 402(a)(4).

You also caused the drug Albon, containing sulfadimethoxine, to become adulterated within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with the labeling. Your use of this drug at levels that exceeded the recommended dosage limits and failure to follow labeled withdrawal periods causes the drug to be unsafe for use.

You should not consider this an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action, without further notice. This may include seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact you caused the adulteration of an animal that was sold and offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing, within 15 working days, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. Your response should be directed to Richard T. Trainor, Compliance Officer, at the following address: FDA, 300 Hamilton Ave., White Plains, New York 10601.

Sincerely,

Jerome G. Woyshner
District Director